

## REMARKS

This communication is submitted in response to the Office Action of December 13, 2004.

Claims 15-20 and 22-24 are pending in the subject application with claim 23 being amended herewith. Claims 15-20, 22 and 24 stand allowed by the Examiner.

The amendments to independent claim 23 are clearly supported by the written description and drawings as originally filed and do not introduce any new matter.

Reconsideration of the subject application is respectfully requested in view of the foregoing amendments and the following remarks.

The rejection of claim 23 as being anticipated by Hirsch et al when taken with Vance, Jr. (Insert Molding-Article) and the Dictionary.com definition of "flange", and the rejection of claim 23 as being unpatentable over Hirsch et al in view of Bodicky, Vance, Jr. and the Dictionary.com definition of "flange" are respectfully traversed for the following reasons.

Independent claim 23 recites "forming a hollow tubular shaft of the ventilation tube from a first material having a rigidity sufficient to resist bending ...; placing the hollow tubular shaft in a first cavity portion of a cavity of a mold wherein the first cavity portion has a part thereof corresponding in configuration to the configuration of the hollow tubular shaft and another part thereof corresponding in configuration to the configuration of a tubular section of a flanged end portion of the ventilation tube to be formed as a longitudinally continuous extension of the hollow tubular shaft extending beyond an end of the hollow tubular shaft to a flange of the flanged end portion to be formed transverse to the hollow tubular shaft, and wherein the cavity has a second

cavity portion transverse to and in communication with the first cavity portion and having a configuration corresponding to the configuration of the flange, said step of placing including placing the hollow tubular shaft in the part of the first cavity portion corresponding in configuration to the configuration of the hollow tubular shaft leaving unoccupied the second cavity portion and the part of the first cavity portion corresponding in configuration to the configuration of the tubular section of the flanged end portion; and forming the flanged end portion of the ventilation tube of a second material, having a rigidity less than that of the first material to permit the flange to deform in response to contact with the anatomical structure in which the hollow tubular shaft is placed, by supplying the second material to the second cavity portion and the unoccupied part of the first cavity portion to form the flanged end portion molded onto the hollow tubular shaft in a finished ventilation tube." As explained below, the steps recited in independent claim 23 are not disclosed by Hirsch et al, considered singly or in any reasonable combination with Vance, Jr., the Dictionary.com definition of "flange" and/or Bodicky.

The structure disclosed by Hirsch et al for the gastrostomy tube 20 dictates that the gastrostomy tube 20 cannot be made pursuant to a method as recited in independent claim 23. In Hirsch et al, the retaining element 24 of gastrostomy tube 20 does not include a tubular section formed as a longitudinally continuous extension of tubular member 21 extending beyond an end 22, 23 of the tubular member 21 to a flange of the retaining element. Rather, the retaining element 24 merely includes petaloid flanges 27, 28, 29 extending outwardly from tubular member 21 and connecting portions 30, 31, 32 between adjacent petaloid flanges. No part of the

retaining element 24 constitutes a tubular section or any other section extending beyond end 22 or 23 of the tubular member 21. According to the explicit teachings of Hirsch et al, an "important" feature of the gastrostomy tube is that the petaloid flanges 27, 28, 29 are less flexible than the connecting portions 30, 31, 32 (column 3, lines 44-47). The petaloid flanges 27, 28, 29 are preferably made of a material having a Shore A durometer in the range of 50 to 80, and the connecting portions 30, 31, 32 preferably are made of a material having a durometer in the range of 10 to 40 Shore A. Another feature identified by Hirsch et al as "important" is that the tubular member 21 comprises a material having a durometer in the range of 30 to 40 Shore A and, most preferably, about 35 Shore A. Accordingly, the petaloid flanges 27, 28, 29 are not formed of a material having a rigidity less than that of the tubular member 21 as is required by claim 23 for the flanged end portion. Although the range of durometers disclosed by Hirsch et al for the connecting portions 30, 31, 32 and the tubular member 21 make it possible for the connecting portions 30, 31, 32 to be less rigid than the tubular member, Hirsch et al does not recognize any relationship whatsoever between the flexibility of the connecting portions 30,31,32 and the flexibility of the tubular member 21. It is just as possible under the teachings of Hirsch et al for the connecting portions 30, 31, 32 to be more rigid than the tubular member 21 and still be more flexible than the petaloid flanges 27, 28, 29. This being the case, Hirsch et al cannot be considered as disclosing the method recited in claim 23 which requires formation of the flanged end portion of a second material having a rigidity less than that of the first material from which the hollow tubular shaft is formed.

Hirsch et al teaches that the tubular member 21 and the petaloid flanges 27, 28,

29 (not the connecting portions 30, 31, 32) may be insert molded together (column 4, lines 58-62). Even if the connecting portions 30, 31, 32 are considered “flanges” based on the Dictionary.com definition of “flange”, these are not the specific “flanges” that Hirsch et al discloses may be insert molded together with the tubular member 21. The description of Hirsch et al clearly distinguishes the petaloid flanges 27, 28, 29 structurally from the connecting portions 30, 31, 32 (column 3, lines 21-25). Therefore, where Hirsch et al discloses that the petaloid flanges 27, 28, 29 and the tubular member 21 may be insert molded together, this disclosure cannot properly be expanded to encompass the connecting portions 30, 31, 32, which are clearly differentiated by Hirsch et al from the petaloid flanges. Accordingly, the teachings in Hirsch et al of insert molding relied by the Examiner is limited to insert molding of the tubular member 21 together with the petaloid flanges 27, 28, 29 formed of a material having greater rigidity than the material of the tubular member 21, and this is in direct contrast to the claimed method.

Contrary to the Examiner’s assertion, Hirsch et al does not state at column 4, lines 1-6, that a two stage molding process, much less a two stage insert molding process, is used to connect the two-piece retaining element of Figs. 1-5 to the tubular member. Rather, the passage relied on by the Examiner states merely that the petaloid flanges are encased in the material which comprises the connecting flanges due to a two stage molding process. This statement provides no teachings or suggestions whatsoever relating to connection of the retaining element 24, which comprises the petaloid flanges and the connecting portions, to the tubular member 21 and also does not teach or suggest the two stage molding process as an insert molding process. The

Examiner has misinterpreted the teachings of Hirsch et al and has expanded the teachings of Hirsch et al beyond the reasonable metes and bounds of its disclosure.

Given that the retaining element 24 of Hirsch et al does not have a tubular section to be formed as a longitudinally continuous extension of the tubular member 21 extending beyond an end 22, 23 of the tubular member to a flange of the retaining element, Hirsch et al does not and cannot teach or suggest the steps recited in claim 23 of placing the hollow tubular shaft in a first cavity portion of a cavity of a mold wherein the first cavity portion has a part thereof corresponding in configuration to the configuration of the hollow tubular shaft and another part thereof corresponding in configuration to the configuration of a tubular section of the flanged end portion to be formed as a longitudinally continuous extension of the hollow tubular shaft extending beyond an end of the hollow tubular shaft to a flange of the flanged end portion to be formed transverse to the hollow tubular shaft, and wherein the cavity has a second cavity portion transverse to and in communication with the first cavity portion and having a configuration corresponding to the configuration of the flange. Furthermore, it follows that Hirsch et al does not and cannot teach or suggest the step of placing recited in claim 23 involving placing the hollow tubular shaft in the part of the first cavity portion corresponding in configuration to the configuration of the hollow tubular shaft leaving unoccupied the second cavity portion and the part of the first cavity portion corresponding in configuration to the configuration of the tubular section of the flanged end portion.

Given that the only teaching in Hirsch et al with respect to molding a flange onto the tubular member 21 involves molding the petaloid flanges 27, 28, 29 of more rigid

material together with the tubular member 21 of less rigid material, Hirsch et al does not and cannot teach or suggest the step recited in claim 23 of forming the flanged end portion of a second material, having a rigidity less than that of the first material from which the tubular shaft is formed. In view of the structural differences between the retaining element 24 of Hirsch et al and the flanged end portion defined in claim 23, Hirsch et al also does not and cannot teach or suggest the step recited in claim 23 of supplying the second material to the second cavity portion and the unoccupied part of the first cavity portion to form the flanged end portion molded onto the hollow tubular shaft in a finished ventilation tube.


Vance, Jr. does not rectify any of the foregoing deficiencies of Hirsch et al with respect to the method claimed in claim 23. Vance, Jr. fails to disclose the limitations discussed above as not being disclosed by Hirsch et al. In addition, Vance, Jr. does not provide any teachings that would make it clear that the limitations discussed above as being absent in Hirsch et al are necessarily present in Hirsch et al.

Bodicky fails to provide any teachings or suggestions combinable with the teachings of Hirsch et al to obtain the claimed method. Bodicky discloses a method for connecting a plastic tube 12 to a plastic hub 14 involving subjecting a selected area of the tube 12 to external heat so that the plastic material swells and produces a bulge, and then inserting the portion of the tube 12 having the bulge in a mold for the hub 14 so that the bulged portion is embedded in the hub. No teachings or suggestion are provided by Bodicky which would impart structure to the gastrostomy tube 20 of Hirsch et al needed in order to make the gastrostomy tube in accordance with the method recited in claim 23.

Accordingly, independent claim 23 is submitted to be clearly patentable over Hirsch et al, considered singly or in any reasonable combination with Vance, Jr., the Dictionary.com definition of "flange" and/or Bodicky, and should be allowed.

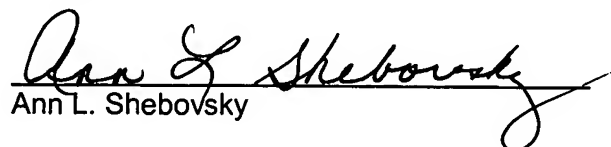
In light of the foregoing, all of the claims in the subject application are submitted to be in condition for allowance. Action in conformance therewith is courteously solicited. Should any issues in the subject application remain unresolved, the Examiner is encouraged to contact the undersigned attorney.

Respectfully submitted,

  
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I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to: MAIL STOP: AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on February 25, 2005.

  
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